SUMMARY OF SAFETY AND PROBABLE BENEFIT

SUMMARY OF SAFETY AND PROBABLE BENEFIT DATA

I. GENERAL INFORMATION

Device Generic Name:	Prosthetic Rib
Device Trade Name:	Vertical Expandable Prosthetic Titanium Rib (VEPTR)
Applicant's Name and Address:	SYNTHES® Spine 1230 Wilson Drive West Chester, PA 19380
Humanitarian Device Exemption Number:	H030009
Date of Humanitarian Use Device Designation:	October 2, 1997
Date of Panel Recommendation:	Not applicable (See Section XII for discussion)
Date of Good Manufacturing Practices Inspection:	October 11, 2000 and July 30, 2002
Date of Notice to the Applicant:	August 24, 2004

II. INDICATIONS FOR USE

The VEPTR is indicated for treatment of Thoracic Insufficiency Syndrome (TIS) in skeletally immature patients. TIS is defined as the inability of the thorax to support normal respiration or lung growth.

For the purpose of identifying potential TIS patients, the categories in which TIS patients fall are as follows:

- Flail Chest Syndrome
- Rib fusion and scoliosis
- Hypoplastic thorax syndrome, including,
  - Jeune's syndrome
  - Achondroplasia
  - Jarcho-Levin syndrome
  - Ellis van Creveld syndrome

III. CONTRAINDICATION

The VEPTR device should not be used under the following conditions:

- Inadequate strength of the bone (ribs/spine) for attachment of the VEPTR
- Absence of proximal ribs for attachment of the VEPTR
- Absent diaphragmatic function
- Inadequate soft tissue for coverage of the VEPTR
- Age beyond skeletal maturity
- Age below 6 months
- Known allergy to any of the device materials
- Infection at the operative site

IV. WARNINGS AND PRECAUTIONS

- Patients implanted with the VEPTR should not be braced. The VEPTR device is designed to allow for thoracic cavity growth and the restrictive nature of a brace would not help the condition, but defeat its purpose.

- Patients may require additional wound protection to prevent inadvertent rubbing or bumping of the wound.

- Patients with a diagnosis of spina bifida should have an occlusive dressing over the wound site to keep the site dry.

V. DEVICE DESCRIPTION

The VEPTR device is made up of a combination of the following titanium part (s):

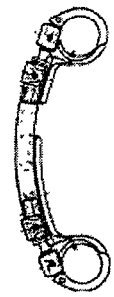
- Superior Cradle
- Inferior Cradle
- Cradle End Half
- Extended Cradle End Half
- Rib Sleeve
- Cradle Lock
- Distraction Lock
- Lumbar Extension
- Low Profile Lamina Hook
- Sacra Ala Hook
- Connector
- 2mm Ti Rod

VEPTR can be assembled into three configurations:

1. *Cradle to Cradle Assembly*

The Cradle to Cradle Assembly is made up of Superior and Inferior Cradles, Cradle End Half (2), and a Rib Sleeve. It is indicated for use when the patient has TIS because of fused or missing ribs, severe scoliosis, and/or hypoplastic thorax.

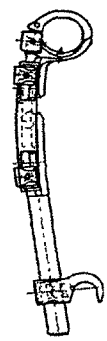
Cradle to Cradle Assembly:



2. ***Cradle with Lumbar Extension Assembly***

The Cradle with Lumbar Extension Assembly is made of the Superior Cradle, Cradle End Half, Rib Sleeve, Lumbar Extension, and Low Profile Lamina Hook. It is indicated for use when no lower ribs exist or when the scoliotic bend goes into the lower lumbar region.

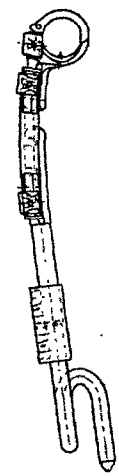
Lumbar Extension Assembly:



3. ***Cradle to Ala Hook Assembly***

The Cradle to Ala Hook Assembly is made of the Superior Cradle, Cradle End Half, Rib Sleeve, Lumbar Extension, and Sacral Ala Hook Assembly. It is used when attachment of the end section of the device to the pelvis is necessary when there are no inferior ribs or when there is inadequate strength in the lumbar vertebrae for attachment.

Ala Hook Assembly:



The end section can be unlocked and made longer, increasing the intercostal space and allowing more space for chest and lung growth.

All device components are manufactured from titanium alloy, Ti-6Al-7Nb (ASTM F1295), with the exception of the Sacral Ala Hook and 2mm Rod, which are manufactured from commercially pure titanium, TiCP4 and TiCP1, (ASTM F67), respectively.

Associated manual instrumentation utilized for the implantation of these components is available for the insertion , distraction, expansion and removal of the VEPTR.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Currently available practices and procedures include both surgical and non-surgical treatments. Non-surgical treatment consists of long-term ventilator support; however, without surgery this condition is frequently terminal.

Surgical treatments for chest wall defects include use of sheets of artificial materials, and, if the patient is old enough, sections of autograft or allograft ribs. Treatment for fused ribs requires splitting the fused ribs and inserting a spacer to prevent the ribs from refusing. Treatment of patients with underdeveloped chests involves splitting the sternum and inserting a spacer to hold it apart. Progressive scoliosis is currently treated by surgical fusion and instrumentation.

VII. MARKETING HISTORY

The VEPTR device has been marketed in Canada. The VEPTR device has not been withdrawn from any market for any reason related to the safety or effectiveness of the device.

VIII. POTENTIAL ADVERSE EVENTS OF THE DEVICE ON HEALTH

From the feasibility and multi-center clinical trials, a total of 247 patients were evaluated for adverse events. The adverse events experienced in the clinical trials are presented in Section X., Clinical Information, below. The following is a list of potential adverse effects that may occur with treatment of TIS with the VEPTR device.

- Failure to stabilize or correct thoracic deformities
- Failure to support normal respiration or lung growth
- Failure to stabilize or correct progressive scoliosis
- Device migration (dislodgment, cut-out)
- Device fracture or bending
- Device disassembly
- Development of allergy to the implant materials (titanium)

- Need for additional surgical procedures, including expansions, replacements, removals
- Infection (abscess, cellulites, fever, pneumonia, urinary tract infections)
- Pain (back, chest, neck)
- Pulmonary (effusions, atelectasis, respiratory distress, respiratory acidosis)
- Skin or wound (dermatitis, rash, skin necrosis, abnormal healing, scar formation)
- Neurologic (peripheral neuropathy, spinal cord injury, dural tear, CSF leak, convulsions, hypokinesis)
- Death

Note: Additional surgery may be necessary to correct some of these potential adverse events.

IX. SUMMARY OF PRECLINICAL STUDIES

Biocompatibility Testing
The VEPTR has not been subjected to biocompatibility testing. The VEPTR components are fabricated from titanium alloy (Ti-6Al-7Nb, ASTM Standard F1295), or commercially pure titanium, TiCP4 and TiCP1, (ASTM Standard F67). These materials have a long and well-documented history of safe use in orthopedic implants.

Mechanical Testing
The non-clinical mechanical tests were conducted to characterize the mechanical properties of the VEPTR. The worst-case constructs of the VEPTR device were subjected to static and fatigue mechanical testing. All system and individual component testing results appear to indicate the VEPTR's ability to withstand normally expected physiologic loads.

1. Low-Profile Lamina Hook Interconnection Strength Test
Five constructs were assembled, consisting of one Low Profile Ti Lamina Hook and one 6mm-diameter Ti hard rod. The Lamina Hook was placed halfway down the length of the rod, and the setscrew was tightened to a torque of 6 N-m. Tests were performed under displacement control, at a rate of 5.0 mm/minute. Load versus displacement was recorded until the occurrence of rod slippage occurred within the hook assembly. Slippage was defined as the load when the slope of the load/displacement curve decreases.

The average slippage load was 2253 N (s.d. 742 N).

2. Distraction Lock Tensile Strength Test
The tensile load required to cause failure of the distraction lock was evaluated on three (3) samples. The fixtures were loaded in tension until the lock failed, at which point the samples were examined for damage.

The average failure load was 520.1 lb (s.d. 32.94 lb). All Locks failed in shear and at the point where the pin transitions from 0.093in diameter to 0.124in diameter. There was no apparent deformation of the samples after testing.

3. Static Compression Test, Longest Lumbar Extension, Rib Sleeve, and S-Hook Assembly

The purpose of the static compression test was to determine the yield point and identify failure modes for the longest VEPTR Lumbar Extension/Sleeve and S-Hook assembly. Five 220mm radius VEPTR assemblies with Lumbar Extensions and S-Hooks were tested in a stroke controlled mode. The mean ultimate load was 419 N, and the ultimate bending strength was 16,758 N-mm.

2% Offset Yield

Specimen	Load (N)	Displacement (mm)	Bending Strength (N-mm)	Bending Stiffness (N/mm)	Bending Rigidity (N)	Elastic Displacement (mm)
Mean ± SD	352 ± 13	19.295 ± 0.436	14061 ± 509	26 ± 0	729 ± 13	13.495 ± 0.436

0.2mm Offset Yield

Specimen	Load (N)	Displacement (mm)	Bending Strength (N-mm)	Bending Stiffness (N/mm)	Bending Rigidity (N)	Elastic Displacement (mm)
Mean ± SD	145 ± 5	5.575 ± 0.166	5808 ± 200	27 ± 0	1042 ± 17	5.375 ± 0.166

The failure mode of all assemblies tested was deformation of the lumbar extension.

4. Fatigue Compression Test, Longest Lumbar Extension, Rib Sleeve, and S-Hook Assembly

The purpose of this test was to evaluate the fatigue strength of the longest VEPTR lumbar extension/sleeve and S-Hook construct. Two 220mm radius VEPTR assemblies including the longest VEPTR lumbar extension sleeve and S-Hook construct in a load controlled mode. Fatigue testing was done at 5 Hz to a run-out of 5 million cycles. Failure was defined as a deviation greater than 10 below the programmed peak to peak load. Both assemblies ran out to 5 million cycles from 10 N to 100 N and reversed. The fracture location was wear at fixture interface.

X. SUMMARY OF CLINICAL INFORMATION

Objective

A prospective, multi-center clinical trial of the VEPTR device was conducted in the United States to determine the safety and effectiveness of the device in the treatment of TIS. All patients enrolled in the study were treated with the VEPTR device and served as their own controls.

Inclusion and Exclusion Criteria
Eligible patients had a primary diagnosis of TIS with a thoracic malformation classified in one of the following categories:

Category I: Flail Chest Syndrome, including congenital chest wall defect, acquired surgical chest wall deficit due to tumor resection, surgical separation of conjoined twins, traumatic flail chest.

Category II: Congenital Constrictive Chest Wall Syndrome, including rib fusion or hypoplastic thorax syndrome; rib fusion with progressive thoracic scoliosis without vertebral anomalies; rib fusion with secondary chest wall constriction by progressive thoracic congenital scoliosis; hypoplastic thorax syndrome; Jeune's syndrome (asphyxiating thoracic dystrophy); achondroplasia; Jarcho-Levin syndrome (lethal autosomal short-trunk dwarfism); Ellis van Creveld syndrome (chondroectodermal dysplasia).

Category III: Progressive scoliosis of congenital or neurogenic origin without rib anomaly.

Patients were 6 months of age or older, up to the age of skeletal maturity, depending on the diagnostic category.

Clinical Trial Design
This was a prospective, single-treatment arm study conducted in two phases: a single investigational site feasibility study and a multi-center pivotal trial.

Patient Population and Demographics
A single site feasibility study with thirty three (33) patients and a multi-center, prospective study at seven (7) sites with two hundred twenty four (224) patients were performed. Two hundred fifty seven (257) patients were studied, but ten (10) patients were excluded from the analysis due to the absence of baseline data. Enrolled patients at each site received the VEPTR device assembly appropriate to disease pathology and anatomical requirements. For the purposes of reporting the results, the study population was divided into four diagnostic categories: Flail Chest, Rib Fusion, Hypoplastic Thoracic Syndrome, and Progressive Scoliosis.

Table 1
Study Population

Study Phase	Diagnostic Category				Total
	Flail Chest	Rib Fusion	Hypoplastic Thoracic Syndrome	Progressive Scoliosis	
Feasibility	6	19	6	2	33
Multi-Center	8	75	87	44	214
Totals	14	94	93	46	247

Table 2 Patient Demographics Feasibility and Multi-Center Studies					
	Diagnostic Category				Total
	Flail Chest	Rib Fusion	Hypoplastic Thoracic Syndrome	Progressive Scoliosis	
N	14	94	93	46	247
Male (%)	8 (57.1%)	49 (52.1%)	43 (46.2%)	24 (52.2%)	124 (50.2%)
Female (%)	6 (42.9%)	45 (47.9%)	50 (53.8%)	22 (47.8%)	123 (49.8%)
Age, mean (years)	5.1	3.7	3.3	5.2	3.9
Age range (years)	0.0-15.0	0.0-14.0	0.0-15.0	0.0-12.0	0.0-15.0

Evaluation Schedule

Clinical examinations were performed at each surgical procedure and at the post-operative follow-up visits at 4 months (±2 months), 8 months (±2 months), 12 months (±2 months), 16 months (±2 months), 20 months (±2 months), 24 months (±4 months), and annually thereafter (±4 months). At each follow-up visit, patients had general physical examinations, measurements of sitting and standing height, chest and abdominal circumference (inspiration and expiration), vital signs, weight, Assisted Ventilation Rating (AVR) (an outcome measure specifically developed for this investigation), Quality of Life Assessment (QOL) (Child Health Questionnaire for children ≥5 years, or Infant/Toddler Health Questionnaire for children <5 years), capillary blood gases, oxygen saturation (pulse oximeter), pulmonary function tests (in children >7 years without developmental delay), and radiographs (for measurements of thoracic dimensions and Cobb angles).

As the patients experienced normal growth and/or as the spine and thorax required further correction, the study device would require expansions or replacement of the components to increase the overall size of the device. As a guideline, children with scoliosis or flail chest syndrome were to be scheduled for expansion of the device when the Cobb angle increased by 5 degrees or greater. Children with hypoplastic thoracic syndrome were to be scheduled for device expansion approximately every 6 months.

Surgical Procedures

After the initial VEPTR surgical procedure, patients were expected to undergo multiple surgical procedures to expand, replace and remove the VEPTR as part of the normal course of treatment in order to further correct chest wall deformities and accommodate for growth. For the 214 Multi-Center patients, there were 1,051 follow-up surgical

procedures, an average of nearly 5 follow-up surgeries per patient. Approximately 75% of these subsequent surgeries were device expansions.

Table 3
Follow-Up Surgical Procedures
(% of patients)

	Diagnostic Category				Total
	Flail Chest	**Rib Fusion**	**Hypoplastic Thoracic Syndrome**	**Progressive Scoliosis**	
Multi-Center, n	8	75	87	44	214
Total procedures (%)	26	339	592	94	1051
Expansion (%)	19 (73.1)	253 (74.6)	442 (74.7)	71 (75.5)	785 (74.7)
Replacement (%)	0	49 (14.5)	78 (13.2)	14 (14.9)	141 (13.4)
Removal (%)	3 (11.5)	9 (2.7)	2 (0.3)	2 (2.1)	16 (1.5)
Other (%)*	4 (15.4)	28 (8.3)	70 (11.8)	7 (7.4)	109 (10.4)

* "Other" surgical procedures included device re-seating or repositioning; partial or total removals; revision of components; implantation of extensions or additional components; wound debridements; drainages; delayed wound closures; incision and drainages; dressing changes; non-orthopedic procedures, including aspiration of pleural effusions, lymph node biopsy, suture removal, tracheotomy closure, laryngoscopy, Porta Cath insertion, inguinal hernia repair, pulmonary lobectomy, bronchoscopy, and gastric tube procedures.

Patient Accountability

There were 33 patients enrolled in the feasibility study and 224 patients enrolled in the multi-center study. Data from ten patients were not available at the time of database closure and were not included in the analysis. Thus, 214 patients from the multi-center study were analyzed.

Of the 247 patients enrolled in either study, 12 patients died and 2 patients withdrew, leaving 233 patients. Within one year of database closure, 215 patients had evaluations, 5 were lost to follow-up, 5 were seen at other study sites after database closure, 3 were seen at an IRB-suspended site, 3 did not require further surgery, 1 lived in New Zealand, and 1 was transferred to another site.

For the feasibility study, the 2-year, 3-year, and 5-year follow-up rates for those time points or greater were 93.5%, 96.6%, and 89.7%, respectively, and for the multi-center study, 85.7%, 95.8%, and 95.0%, respectively.

Effectiveness Data

- **Assisted Ventilatory Rating (AVR) Outcomes**

Standard pulmonary function test measurements, such as *forced expiratory volume* (FEV), *maximal voluntary ventilation* (MVV), *residual volume* (RV), and *total lung capacity* (TLC), were not feasible in this population because most patients were less than 7 years old and/or developmentally delayed and were unable to follow directions required for these tests. Therefore, the Assisted Ventilatory Rating (AVR) was used to assess treatment effectiveness. AVR outcomes were determined relative to preoperative baseline score. AVR scores were defined as follows:

+0: room air
+1: supplemental oxygen
+2: night ventilation
+3: part-time ventilation or CPAP
+4: full-time ventilation

The AVR outcomes demonstrated improvement or stabilization in 84.4% of patients for the feasibility study and 93.4% of patients for the multi-center study, or 92.0% of patients overall. Each of the diagnostic categories demonstrated improvement or stabilization AVR outcomes.

Table 4
AVR Outcomes

	Diagnostic Category				Total
	Flail Chest	**Rib Fusion**	**Hypoplastic Thoracic Syndrome**	**Progressive Scoliosis**	
Feasibility	3 (50.0)	17 (94.4)	5 (83.3)	2 (100.0)	27 (84.4)
Multi-Center	7 (100.0)	62 (92.5)	71 (91.0)	29 (100.0)	169 (93.4)
Combined	10 (76.9)	79 (92.9)	76 (90.5)	31 (100.0)	196 (92.0)

- **Thoracic dimensions**

The goal of treatment with VEPTR was to equilibrate the height of each individual hemithorax and maintain this correction with each expansion of the devices. Table 5 shows the number and percentage of the subjects who met this goal of treatment, allowing growth of the thoracic spine and increase in the hemithoracic height and volume.

- **Cobb Angle**

The Cobb angle is a measurement of the patient's spinal curvature. A decrease in Cobb angle represents an improvement. For this study, maintenance was defined as stabilization (±5 degree change from baseline) or improvement (>5 degree reduction

from baseline) of the Cobb angle. The Cobb Angle outcomes for this study ranged from are noted in Table 5.

Table 5
Device Outcomes

	Flail Chest	Rib Fusion	Hypoplastic Thoracic Syndrome	Progressive Scoliosis
Multi-Center, n	8	75	87	44
Thoracic Ht Outcome	4 (80.0)	54 (91.5)	56 (84.8)	24 (77.4)
Hemithoracic Ht (Initial Side) Outcome	4 (80.0)	50 (86.2)	58 (90.6)	23 (88.5)
Hemithoracic (Secondary Side) Ht Outcome	3 (60.0)	42 (72.4)	52 (80.0)	16 (59.3)
Hemithoracic Width (Initial Side) Outcome	3 (60.0)	48 (81.4)	54 (83.1)	20 (74.1)
Hemithoracic Width (Secondary Side) Outcome	4 (80.0)	45 (76.3)	53 (81.5)	15 (53.6)
Cobb Angle Outcome	5 (100.0)	51 (83.6)	47 (73.4)	24 (80.0)

Safety Analysis

Twenty-nine of 33 patients in the feasibility study had 408 adverse effects, while 119 of 214 patients (56%) in the multicenter study had 1,051 adverse effects. Respiratory problems such as pneumonia and dyspnea and other conditions, such as fevers, were frequently encountered during the study. These adverse effects are categorized into the following groups:

Table 6
Adverse Events

	Feasibility		Multi-Center	
	Events[1]	Patients[2]	Events[1]	Patients[2]
Totals	408	29	1051	119
Device-Specific	37	16 (48%)	52	34 (16%)
-Device Migration	25	14 (42%)	49	34 (16%)
-Device Failure	13	7 (21%)	6	5 (2%)
-Device Other	1	1 (3%)		
Body as a Whole	9	5 (15%)	47	29 (14%)
-Abscess	1	1 (3%)	13	8 (4%)
-Infection	4	2 (6%)	11	10 (5%)

-Infection, bacterial			4	4 (2%)
-Infection, fungal			2	2 (1%)
-Pain			6	5 (2%)
-Cellulitis	1	1 (3%)		
-Pain, headache	1	1 (3%)		
-Pain, back	1	1 (3%)	2	2 (1%)
-Pain, chest			1	1 (0%)
-Pain, neck			1	1 (0%)
-Fever	1	1 (3%)	3	3 (1%)
-Injury			3	3 (1%)
-Necrosis			1	1 (0%)
Respiratory			16	11 (5%)
-Pneumonia			6	6 (3%)
-Effusion			3	3 (1%)
-Pneumothorax			3	3 (1%)
-Atelectasis			1	1 (0%)
-Respiratory Disorder			1	1 (0%)
-Respiratory Distress Syndrome			1	1 (0%)
-Acidosis, respiratory			1	1 (0%)
Skin and Appendages			13	7 (3%)
-Dermatitis			11	5 (2%)
-Healing, abnormal			1	1 (0%)
-Rash, vesicular			1	1 (0%)
-Injury, accidental	1	1 (3%)		
Metabolic and Nutritional	5	3 (9%)	4	4 (2%)
-Healing, abnormal	5	3 (9%)	4	4 (2%)
Nervous			4	3 (1%)
-Neuropathy	1	1 (3%)		
-Transient Spinal Cord	1	1 (3%)		
-Convulsion			1	1 (0%)
-Hypokinesis			1	1 (0%)
Urogenital	1	1 (3%)		
-Infection, urinary tract	1	1 (3%)		

1 Number of individual adverse events
2 Number of patients experiencing an adverse event

There were 4 intraoperative complications reported for the feasibility and multi-center studies (1.9% of all patients), including a technical error in device placement; a dural laceration, and pressure on the brachial nerve. Sixteen feasibility patients, or 48%, experienced 37 device-specific adverse events, and 34 multi-center patients, or 16%, experienced 52 device-specific adverse events. These device-specific adverse events included device fractures, device migrations, and other device-related adverse events. Device migrations occurred frequently—25 migrations in the feasibility study and 49 migrations in the multi-center study. They were more common with the cradle-to-lumbar

extension and cradle-to-sacral ala assemblies (these two configurations undergo greater flexion, extension, rotation and lateral bending forces than the cradle to cradle assemblies, which are primarily subjected only to the forces of respiration because they function rib to rib). Device migration describes the shift of the superior rib cradle proximally into the rib of attachment, or the distal hook migration through the lamina causing dislodgement, or "disattachment." Some of these reported device migrations "through" bone were actually bone growing around the superior cradle giving the appearance of device migration. Some cradles actually eroded through the bone and emerged superior to the rib into the surrounding muscle.

There were 13 device fractures in 7 of 33 patients in the feasibility study, and 6 device fractures in 5 of 214 patients in the multi-center study. When the total number of actual surgical procedures (initial surgeries, expansions and replacements) are considered, the rate of device fractures were 3.3% in the feasibility study (13 events in 398 procedures) and 0.5% in the multi-center study (6 events in 1,140 procedures). There were 50 procedure-related infections in the 1,538 surgical procedures for the feasibility and multi-center studies (3.3%).

During the course of this 14-year study, there were 12 deaths among the 257 patients enrolled in the study, 4 in the feasibility study and 8 in the multi-center study. None of the deaths were determined by the investigators to be related to the study device.

XI. RISK PROBABLE BENEFIT ANALYSIS

TIS is a life threatening condition that affects a small population of children (less than 4,000 cases per year in the United States). TIS can be seen in any three (3) of the following general diagnostic categories:

- Flail Chest Syndrome
- Rib fusion and scoliosis
- Hypoplastic thorax syndrome

The patient population of this study is a heterogeneous mixture with respect to underlying cause (genetic, congenital, or acquired), severity of symptoms, age, individual patient growth pattern, overall health and other medical conditions concurrent with TIS. Each child with TIS presents a unique combination of factors that dictate the breadth of treatment required. Surgical treatments for these patients have included *in situ* spinal fusion, implantation of plastic sheets, artificial ribs from cadaver donor ribs or autograft rib (rib sections split from contralateral ribs). However, these are static treatments and are not adaptable as the child grows.

Treatment with the VEPTR device has been shown to maintain or improve the AVR in 92.0% of the patients, and the patient survival rate in the VEPTR clinical trial was 95.1%, whereas this condition is frequently terminal with non-surgical treatment. In addition, the ability of the VEPTR to be expanded allows growth of the thoracic spine and lungs while controlling severe scoliosis.

Depending on the presenting condition of the patient, any number of risks may be associated with the implantation and maintenance of the VEPTR device. The adverse events experienced in the VEPTR clinical study were presented in Table 6. Consideration also needs to be given to the age of the patient at initial implantation, the numerous other congenital anomalies these patients can have, and their activity levels. In addition, there are numerous factors that predispose these patients to wound infections, and the use of a prophylactic pre-operative and post-operative antibiotic regime and protective bandages at the operative site may decrease the wound infection rate.

The probable benefits associated with patients implanted with the VEPTR device outweigh the risks present for this patient population.

XII. PANEL RECOMMENDATION

This HDE was not taken to a meeting of the Orthopedics and Rehabilitation Devices Panel because CDRH has determined that the safety profile for the VEPTR device has been adequately characterized through pre-clinical and clinical testing for use in this patient population.

XIII. CDRH DECISION

CDRH has determined that, based on the data submitted in the HDE, that the Vertical Expandable Prosthetic Titanium Rib (VEPTR) will not expose patients to an unreasonable or significant risk or illness or injury, and the probable benefit to health from using the device outweighs the risks of illness or injury, and issued an approval order on August 24, 2004.

XIV. APPROVAL SPECIFICATIONS

Directions for use: See the Physicians Labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the labeling.

Post approval Requirements and Restrictions: See Approval Order